

## **REMARKS**

### **I. INTRODUCTION**

Applicants have invented novel biodegradable thermoplastic compositions that can be processed into a thermoplastic melt that is extruded, blown or cast into sheets and films having desired properties. Like conventional thermoplastic polymers, the thermoplastic compositions are heated so as to make them plastically deformable and then cooled in order to cause one or more thermoplastic polymers contained therein to solidify in order to yield a final sheet or film having desired properties. Unlike conventional thermoplastic polymers (*e.g.*, polyethylene, polypropylene, polyvinyl chloride, and the like) the thermoplastic compositions of the present invention are biodegradable and can be processed or modified to have other properties not found in conventional sheets and films formed from.

### **II. PRIOR ART REJECTION**

The Office Action rejects claims 1-38 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,168,857 to Andersen et al. The Office Action also rejects claims 1-38 under 35 U.S.C. § 103 as being obvious over Andersen et al. Upon reviewing the grounds for rejecting the claims in the first and second Office Actions, it has become clear to Applicants that there remains a fundamental misunderstanding of the characteristics and properties of the sheets and films manufactured according to the present invention and how such sheets and films differ from the teachings of Andersen et al.

In order to assist the Examiner in better understanding what Andersen et al. teaches, Applicants are providing the declaration of Per Just Andersen, Ph.D., the first named inventor in Andersen et al., under 37 § 1.132 (hereinafter "Andersen Decl."), which is attached hereto as Exhibit A.

Applicants have also amended the independent claims to emphasize what was inherent in the claims as originally presented, namely, that the inventive sheets and films are manufactured by processing "a thermoplastic melt formed from a biodegradable thermoplastic composition" (underlining to show added claim language). That the sheets or films are made from a thermoplastic melt is inherent from the claims as originally filed and from the extensive discussion throughout the application relating to the melting points, melting ranges, and glass transition temperatures of the various biodegradable polymers that can be used to form the

biodegradable composition. Processing the biodegradable composition so as to form a "thermoplastic melt" is expressly described at page 49, line 7 of the specification and is implicit in each of the examples.

In contrast, Andersen et al. neither teaches nor suggests the manufacture of sheets or films by extruding, blowing or casting a thermoplastic melt that is then solidified by cooling. Instead, the compositions according to Andersen et al. comprise moldable compositions that are plastic as a result of the inclusion of water. Col. 5, lines 47-61; col. 14, lines 14-18; col. 20, line 1 – col. 21, line 5. As such, the compositions are plastic at room temperature, much like dough or batter that is cooked to form food items. Moreover, rather than cooling a thermoplastic melt so as to form solidified sheets or films, Andersen et al. teaches the very opposite—heating the compositions to drive off water by evaporation in order to cause the starch and auxiliary binder to precipitate and form a solid. Col. 5, line 62- col. 6, line 14; col. 39, line 24 – col. 40, line 13; col. 48, lines 56-59; Andersen Decl., ¶ 10. Andersen et al. neither teaches nor suggest any process whereby the starch and auxiliary binder are in the form of a thermoplastic melt that can be shaped and then cooled to cause it to become solidified in a desired shape. Andersen Decl., ¶ 9.

In view of the foregoing, both the compositions used to manufacture sheets and films according to the present invention, as well as the processes used to manufacture the sheets and films, yields sheets and films that have different properties than the sheets manufactured according to Andersen et al. In particular, sheets and films manufactured from a thermoplastic melt have identifiable properties that distinguish them from sheets or films that are manufactured from aqueous compositions in which the binder is solidified by removing water by evaporation. Andersen Decl., ¶ 15. Indeed, Andersen et al. expressly distinguished the aqueous starch-based compositions disclosed therein from thermoplastic forms of starch (*i.e.*, destructurized starch) that are heated to form a "hot melt" which is solidified by cooling the hot melt". Col. 3, line 59 – col. 4, line 4. Thus, Andersen et al., by its own teachings, discloses compositions and processes that yield final articles that are different from those formed from thermoplastic compositions such as thermoplastic starch.

Finally, Applicants incorporate their previous arguments sets forth in the previously-filed amendments as to why the claims are patentable over Andersen et al. The Office Action fails to show where Andersen et al. teaches or suggests each and every limitation set forth in each of the

claims. Accordingly, it is Applicants' opinion that the Office Action fails to state *prima facie* anticipation and obviousness rejections.

With respect to claim 1, the Office Action asserts, without providing any supporting evidence, "that whenever a film is formed from a composition, it is invariably stretched in one or two directions". In response, Applicants again point out that Andersen et al. neither teaches nor suggests stretching the sheets formed therein, but instead teaches processes whereby the sheets are compressed during formation and prior to solidification. During initial sheet formation from the moldable composition, both the sheet forming process using rollers, as well as the optional extrusion process that may be used to feed the composition between the forming rollers, cause the moldable composition of Andersen et al. to be compressed, not stretched. Andersen Decl., ¶¶ 11-12. Compressing a composition and sheet is the opposite of stretching, which necessarily involves exerting a tensile force, not a compressive force, onto a sheet or film. Andersen Decl., ¶ 12.

Thus, the major premise underlying the Office Action's asserting that claim 1 is not patentable over Andersen et al., namely "that whenever a film is formed from a composition, it is invariably stretched in one or two directions", is false. In fact, Dr. Andersen himself manufactured sheets according to Andersen et al. without stretching them and is therefore of the opinion that the foregoing statement is false. Andersen Decl., ¶ 13. Moreover, the following statement in the Office Action that "such a stretching step is quite well-known in the art" is entirely irrelevant in the context of the applied art, which specifically does not teach or suggest stretching. The Office Action has not identified any teaching or suggestion in the prior art to modify the compositions and methods of Andersen et al. to permit stretching so as to result in cavitation. Absent such a teaching or suggestion, there can be no *prima facie* obviousness. Moreover, the Office Action has not identified any teaching in the prior art that would establish a likelihood of success if one were to modify the compositions and processes of Andersen et al. to permit stretching so as to yield cavitation. In any event, it is not permissible for an examiner to simply state that a particular process is "well-known and therefore obvious". Instead, an examiner is required to provide some teaching or suggestion in the prior art that would have motivated one of skill in the art to modify Andersen et al. to obtain the invention claimed in claim 1. The Office Action fails to do this.

Accordingly, Applicants submit that claim 1 is patentable over Andersen et al., either alone or in combination with any other prior art of record. Dependent claims 2-15 are likewise patentable for the at least the same reasons. In addition, they may include additional limitations that serve to further distinguish over Andersen et al. For example, Andersen et al. neither teaches nor suggests the specific compositions recited in claims 13 and 14. Whereas Andersen et al. may disclose some polymers that happen to be soft and some that happen to be stiff, the Office Action has identified no teaching or suggestion in Andersen et al. for combining them in the manner recited in claims 13 and 29. The Office Action also fails to identify any teaching or suggestion for "thermoplastic starch that is free of plasticizers" as recited in claim 14. The Office Action also fails to identify any teaching or suggestion for combining hard and soft synthetic biodegradable polymers as recited in claims 26, 30, 35 and 37.

Independent claims 1, 16, 18, 32 and 36, as well as the claims which depend therefrom, are patentable over Andersen et al. because they define sheets or films that are manufactured from "a thermoplastic melt". As such, the inventive sheets and films are patentable over Andersen et al., which instead discloses sheets that are manufactured by removing water by evaporation from an aqueous moldable mixture (like forming a pancake). Whereas the compositions used to manufacture the sheets and films of the present invention must be heated to form a thermoplastic melt that is later cooled to form the claimed sheets and films, the compositions used to manufacture sheets according to Andersen et al. contain enough water to allow them to be formed into green sheets without heating. Such green sheets are then hardened or solidified by heating to remove water. This is the very opposite of cooling a thermoplastic melt to yield a hardened sheet. As such, the compositions of Andersen et al. behave exactly opposite to the compositions disclosed in the present application. As a result, the sheets and films manufactured from the inventive thermoplastic compositions will inherently differ from the sheets manufactured from the aqueous compositions of Andersen et al. This conclusion is confirmed by Dr. Andersen, who states that, among other things, starch-based sheets made according to Andersen et al. have higher crystallinity than starch-based sheets formed from a thermoplastic melt. Andersen Decl., ¶¶ 14-15. Of course, to the extent that the sheets and films of the present invention do not contain starch, they are further distinguished from Andersen et al., which requires the inclusion of starch as a binder. Col. 15, lines 15-18.

Claims 31 and 32 are further patentable because the Office Action has not identified any teaching or suggestion in Andersen et al. that the sheets formed therein have particles that protrude from the surface. Instead, the Office Action merely asserts that "Andersen uses extrusion to form sheets" as if that alone settles the question. It clearly does not. First, the Office Action has not provided any basis for asserting that merely extruding the aqueous moldable compositions of Andersen et al. would inherently result in particles protruding from the sheet surface. Second, and more importantly, Andersen et al. does not disclose extrusion as a sheet-forming method. Instead, extrusion, if employed at all, is only used to feed the moldable composition between the sheet forming rollers. Col. 7, lines 13-17; col. 27, lines 40-45; col. 34, lines 36-40. As such, even if the extruded intermediate green sheet had particles protruding therefrom, such particles would be pushed back into the soft composition by the forming rollers to thereby yield a smooth sheet with no protruding particles. The Office Action fails to provide any contrary evidence to rebut Applicants' position that sheets that are passed between one or more sets of sheet-forming rollers would inherently have a smooth surface with no particles protruding therefrom. Instead, it selectively quotes from the foregoing passages, conveniently ignoring the step of passing the extruded sheet between the sheet forming rollers. The argument in the Office Action is therefore entirely nonresponsive to the previously-filed amendments.

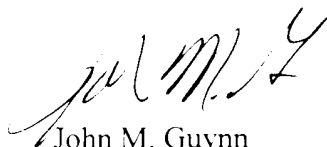
Finally, claim 36 recites "a biodegradable thermoplastic composition that consists essentially of at least one synthetic thermoplastic biodegradable polymer and at least one type of filler particles" (emphasis added). The connector "consists essentially of" means that the biodegradable thermoplastic composition must solely or primarily comprise the synthetic thermoplastic biodegradable polymer and filler. It cannot contain a major proportion of starch, as is taught in Andersen et al. Col. 1, lines 24-26 ("the present invention relates to sheets and films having a binding matrix based on starch"). Although Applicants previously argued in Amendment A that Andersen et al. discloses compositions that include a major proportion of starch, which is obviously a natural, not a synthetic polymer, the Office Action failed to address this. Accordingly, the Office Action is entirely nonresponsive relative to Applicants' arguments relative to claim 36, which therefore presently stands unrejected over any prior art reference.

### III. CONCLUSION

In view of the foregoing, Applicants believe the claims as now presented are in allowable form. In the event that the Examiner finds any remaining impediment to the prompt allowance of this application, which could be clarified by a telephonic interview, or which is susceptible to being overcome by means of an Examiner's Amendment, the Examiner is respectfully requested to initiate the same with the undersigned attorney.

Dated this 21<sup>st</sup> day of August 2003.

Respectfully submitted,



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